

### **REMARKS**

Applicants respectfully request further examination and reconsideration in view of the above amendments and the arguments set forth fully below. In the Office Action mailed May 21, 2007, claims 1-4, 6-10, 13-20 and 41 have been rejected, claim 1 has been objected to, and the specification has been objected to. In response, the Applicants have submitted the following remarks, amended claims 1, 10, 14, 41 and 42 and cancelled claim 7. Accordingly, claims 1-4, 6, 8, 10, 12-20 and 41-42 are now pending. Favorable reconsideration is respectfully requested in view of the above amendments and the remarks below.

### **Specification**

Within the Office Action, the title of the invention is deemed not descriptive, and the Examiner has required a new title that is clearly indicative of the invention to which the claims are directed. By the above amendment, the Applicants have amended the title according to the Examiner's suggestion, and therefore respectfully requests that the objection to the specification be withdrawn.

### **Claim Objections**

Claim 10 has been objected to because it is stated that there appears to be an inadvertent typographical error in the claim, specifically having to do with the dependency of claim 10. By the above amendment, the Applicants have amended claim 10 to show the appropriate dependency, and therefore respectfully request that the Examiner withdraw the objection to claim 10.

### **Rejections Under 35 U.S.C. §112**

Claims 10, 14 and 41 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. Specifically as to claims 10 and 41, the Examiner has indicated that he is unsure whether the term "threshold" is different

from the term “probability constant.” By the above amendments, the Applicant has amended claims 10 and 41 according to the Examiner’s suggestion. The Applicants therefore respectfully request that the Examiner withdraw the rejections of claims 10 and 41 under 35 U.S.C. §112, second paragraph.

It is stated within the Office Action that claim 14 recites the limitation “the measurements” in the second line of the claim and that there is insufficient antecedent basis for this limitation in the claim. As stated within the Office Action that claim 14 also recites the limitation “the blood pressure” and that there is also insufficient antecedent basis for this limitation in the claim. By the above amendment, the Applicant has amended claim 14 to include limitation that have antecedent basis, and therefore respectfully request that the Examiner withdraw the rejection to claim 14 under 35 U.S.C. §112, second paragraph.

#### Rejections Under 35 U.S.C. §101

Claims 1-4, 6, 8, 10, 12-20 and 41-42 have been rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter, specifically, it is stated within the Office Action that the claims are directed to a judicial exception in that the method claims relate to abstract ideas rather than practical applications of those ideas. By the above amendments, the Applicant has amended the independent claims 1, 41 and 42 to include the limitation of claim 7, as suggested by the Examiner. Therefore, the Applicants respectfully request that the rejections to the independent claims 1, 41 and 42 be withdrawn. Accordingly, the Applicants respectfully request that the Examiner withdrawn the rejection under 35 U.S.C. §101 of claims 2-4, 6, 8, 10 and 12-20 as they depend upon the independent claim 1.

#### Rejections Under 35 U.S.C. §103

Claims 41 and 42 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Publication No. 2004/0215090 to Erkkila (hereinafter

Erkkila) in view of U.S. Patent Publication No. 2002/0133087 to Bayer et al. (hereinafter Bayer). The Applicant respectfully disagrees with this rejection.

Erkkila teaches a method and apparatus for predicting a sudden heart abnormality for an individual patient. Within the Office Action it is stated that the server 604 of Erkkila exists as one of a plurality of health flow locations, and the bedside apparatus in Figure 6 of Erkkila exists as another one of the plurality of healthcare locations. By the above amendments, the Applicant has further clarified the claims to include the step of acquiring patient data from a plurality of healthcare locations, wherein each of the plurality of healthcare locations includes a patient monitor. Erkkila does not teach such functionality. In other words, the Erkkila reference is not a distributed system that includes a plurality of healthcare locations that are configured to collect patient data for assessment purposes.

The Bayer reference is a patient monitor for determining the probability that a patient has acute cardiac ischemia including an input device connectable to a patient to acquire ECG signals from the patient. Again, the Bayer reference is not a distributed system configured to collect patient data from a plurality of locations in order to assess cardiac death for a patient.

In contrast to the teachings of Erkkila and Bayer, the method of the present invention includes a distributed development or capability that includes multiple test collections at multiple healthcare locations such that a patient's risk of sudden cardiac death would be assessed. Neither Erkkila, Bayer nor their combination teach such distributed functionality.

The independent claim 41 is directed to a method of assessing a risk of sudden cardiac death for a patient, the method comprising acquiring patient data from a plurality of healthcare locations, wherein each of the plurality of healthcare locations includes a patient monitor; identifying the patient as being worthy of an on-going sudden cardiac death risk assessment based on the acquired patient data; performing the on-going sudden cardiac death risk assessment whenever new patient data is acquired at any one of the

plurality of healthcare locations; calculating a probability of sudden cardiac death for the patient based on at least one of the new patient data and a medical history of the patient; alerting a healthcare provider if the probability of sudden cardiac death is greater than the probability constant; comparing the probability of sudden cardiac death to at least one probability constant to determine a risk level; further comprising selecting the at least one probability constant for a specific patient; and displaying an assessment of sudden cardiac death risk on a patient monitor. As discussed above, neither Erkkila, Bayer nor their combination teach the distributed system of the present invention that is configured to acquire patient data from a plurality of healthcare locations, wherein each of the plurality of healthcare locations includes a patient monitor. For at least these reasons, the independent claim 41 is allowable over the teachings of Erkkila, Bayer and their combination.

The Applicant respectfully submits that the independent claim 42 is allowable over the teachings of Erkkila, Bayer and their combination for the same reasons as discussed above with respect to the independent claim 41.

Claims 1-4, 6-8, 10, 12-15, 17-18 and 20 have been rejected under 35 U.S.C. §102(a) as being unpatentable over Erkkila in view of Bayer, and further in view of U.S. Patent No. 6,517,480 to Krass (hereinafter Krass). The Applicants respectfully disagree with this rejection. The Applicants have deleted from the independent claim 1 the limitation that the Examiner intended Krass to anticipate, and therefore, the Applicants respectfully submit that the independent claim 1 is allowable over the teachings of Erkkila, Bayer and Krass for the same reasons as discussed with respect to the independent claims 41 and 42.

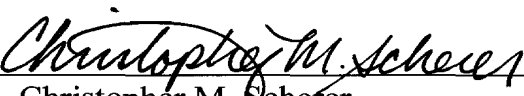
Claims 2-4, 6, 8, 10 and 12-20 are dependent upon the independent claim 1. As discussed above, claim 1 is allowable over the teachings of Erkkila, Bayer, Krass, and their combination. Accordingly, claims 2-4, 6, 8, 10 and 12-20 are also allowable as being dependent upon an allowable base claim. Claim 7 has been cancelled.

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For these reasons, Applicants respectfully submit that all of the claims are now in a condition for allowance, and allowance at an early date would be appreciated. Should the Examiner have any questions or comments, they are encouraged to call the undersigned at 414-271-7590 to discuss the same so that any outstanding issues can be expeditiously resolved.

Respectfully submitted,

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